

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 8 is drawn to a method of visibly reducing a human skin wrinkle comprising topically applying an IRM compound that is an agonist of TLR7, TLR8, or both TLR7 and TLR8, classified in class 514, subclass 365, and 374 for example.
- II. Claims 12-20 and 26-32, are drawn to a method for treating fine lines or clinical wrinkles wherein the skin is not being treated for viral infection or skin cancer comprising essentially applying an imidazoquinoline amine derivative of claim 12, classified in class 514, subclass 396 for example.
- III. Claims 21-22, are drawn to a method of inducing an immune cytotoxic response in wrinkles not being treated for viral infection or cancer, comprising topically applying a compound of claim 21 whereby improvements are seen in 4 weeks, classified in class 514, subclass 396.
- IV. Claims 23-26, are drawn to a method of identifying a precancerous region of skin comprising topically applying to fine lines or wrinkles a composition comprising 1-isobutyl-1H-imidazo[4,5,c]quinolin-4-amine and monitoring

the physical appearance of the region of skin, whereby a precancerous region becomes inflamed or irritated following application of the composition, classified in class 514, subclass 396.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group I to Group III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different designs and/or effects. Particularly, the method of Group I uses a vast amount of compounds that specifically must be an agonist of TLR7, TLR8 or both TLR7 and TLR8, while Group II is drawn to a method comprising essentially of imidazoquinoline amine derivatives in claim 12. Additionally, Groups III and IV are drawn to a different effect. Group III is drawn to a method of inducing an immune cytotoxic response in wrinkles not being treated for viral infection or cancer, comprising topically applying a compound of claim 21 whereby improvements are seen in 4 weeks. Group IV is drawn to a method of identifying a precancerous region of skin with one specific compound.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above

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and there would be a serious search and/or examination burden if restriction were not required because at least the following reason(s) apply:

The methods are unrelated as being drawn to different effects or/and elements of the claim (i.e. compound).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is

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the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Claims 8 is generic to the following disclosed patentably distinct species: an compound. The species are independent or distinct because each sub-species of IRM compounds claimed have different core structures . In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is a search and/or examination burden for the patentably distinct species as set forth above because at least the following reason(s) apply:

each sub-species of IRM compounds claimed have different core structures and would require a separate distinct search.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or a grouping of patentably indistinct species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species or grouping of

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patentably indistinct species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species or grouping of patentably indistinct species.

Should applicant traverse on the ground that the species, or groupings of patentably indistinct species from which election is required, are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing them to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Due to the complexity of the restriction requirement, a telephone call was not made to request an oral election to the above restriction requirement.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KENDRA D. CARTER whose telephone number is (571)272-9034. The examiner can normally be reached on 9:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kendra D Carter
Examiner, Art Unit 1627

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627